



NATIONAL ACTION PLAN ON BREAST CANCER A Public/Private Partnership

W O R K I N G G R O U P

JANUARY 1999

THE CLINICAL TRIALS ACCESSIBILITY WORKING GROUP

Research studies on breast cancer, called clinical trials, involve patients and individuals at risk for breast cancer in research efforts to develop new and more effective treatments and prevention strategies. By comparing promising therapies with standard (current) approaches, clinical trials help scientists and clinicians determine whether the new treatments and techniques are safe and effective and whether they are better than existing methods. These trials test a range of issues, including new ways

of detecting and diagnosing cancer; strategies for improving physical and psychological quality of life for those with breast cancer and those undergoing treatment; and new drugs, drug combinations, or surgical procedures for treating breast cancer. Clinical trials are conducted in many settings, including cancer centers, universities, community hospitals, and doctors' offices. These studies play a critical role in continuing progress against cancer and are a fundamental link between basic research discoveries and improved patient care.

However, clinical trials rely on the participation of breast cancer patients and those at risk for breast cancer. Currently, a very small percentage of all eligible cancer patients participates in clinical trials. The reasons for this low level of participation are complex, involving both patient and physician issues. Patients may not be knowledgeable about clinical trials, their purpose and benefits, where they are being conducted, or how to get information about participating. Some patients express concern about the severity of the experimental treatment or the possibility of being randomly assigned to standard treatment; potential increased inconvenience related to participation, such as transportation and travel time; or insurance coverage for experimental treatment.

Physicians also may lack sufficient information to feel comfortable recommending clinical trials for their patients. They may be concerned that the experimental treatment is not as effective as the standard treatment, that they will lose patients to the doctors and institutions conducting the trial, or that administrative costs and time associated with patient participation will increase.

Additional barriers to participation may be posed by geographically inconvenient locations, restrictive entry criteria, complex trials, or a limited number of trials addressing a specific breast cancer issue.

The National Action Plan on Breast Cancer's (NAPBC's) Clinical Trials Accessibility Working Group was formed to address this

WHAT IS THE NAPBC?

The National Action Plan on Breast Cancer (NAPBC) was established in 1993 in response to a National Breast Cancer Coalition petition signed by 2.6 million people and presented to President Clinton. The petition called for a coordinated national strategy to combat breast cancer, the second leading cause of cancer deaths among American women.

The mission of the NAPBC is to stimulate rapid progress in eradicating breast cancer. The strategy for the Plan is to:

- *encourage new ideas and define unaddressed breast cancer priority areas.*
- *serve as a catalyst for national efforts to advance breast cancer knowledge, research, policy, and services.*
- *mobilize partnerships and coordinate actions among diverse public and private sector organizations and individuals.*

The work of the NAPBC is guided by a Steering Committee and Working Groups. The Steering Committee provides oversight for and ensures coordination across NAPBC initiatives. The Working Groups correspond to Plan priorities and identify, recommend, and oversee implementation of Plan activities. Plan implementation is coordinated by the U.S. Public Health Service's Office on Women's Health. Currently, there are five Working Groups. This fact sheet describes the Clinical Trials Accessibility Working Group.

priority area. Its charge is to find ways to make clinical trials more widely accessible to women with breast cancer and women who are at high risk for breast cancer. This involves identifying barriers to participation in clinical trials and developing strategies to overcome these barriers.

CURRENT ACTIVITIES AND ACCOMPLISHMENTS

The Clinical Trials Accessibility Working Group has been working on several initiatives to address the key barriers associated with low participation in breast cancer clinical trials by patients and physicians. Several coordinated activities are being conducted to increase access to clinical trials information and knowledge about clinical trials.

Strategies for a National Awareness Campaign about Clinical Trials

Background research and consultation with social marketing experts in preparation for a national awareness campaign about clinical trials have been completed. The Working Group also has completed an extensive literature search, conducted personal interviews with patients and physicians knowledgeable about clinical trials accrual, reviewed preliminary results from research studies supported by the NAPBC, and gathered information about related efforts by the National Cancer Institute (NCI) and other public and private sector agencies. A focus group report containing strategies for conducting a national awareness campaign will be submitted for publication.

Review of Research on Barriers to Participation in Clinical Trials

The Working Group has conducted a systematic literature review of studies identifying physician and patient barriers to patient participation in randomized controlled clinical trials (RCTs), with a particular interest in barriers relevant to participation in breast cancer RCTs. The findings will be submitted for publication in the spring of 1999.

Information on Clinical Trials

The Working Group is exploring ways to make information about clinical trials more accessible and user-friendly. The Working Group has coordinated meetings with Federal and private sector organizations involved in developing clinical trials information to discuss advantages and disadvantages of current registries and to develop ways to improve and integrate them. In addition, links to information on clinical trials have been established on the NAPBC Web site (<http://www.napbc.org>).

Informed Consent and Insurance Reimbursement Issues

Working Group members are participating in government and private sector groups that address informed consent and insurance reimbursement issues related to participation in clinical trials. This involvement, and the strong partnerships with a range of organizations and agencies that result, will ensure that the special concerns of breast cancer patients and those at high risk of breast cancer are considered in decisions related to these issues.

FUTURE PLANS

In future months, the Working Group will recommend a detailed strategy for conducting the national clinical trials awareness campaign. Members also will continue their active participation in public and private sector groups concerned with informed consent and insurance reimbursement.

OTHER SOURCES OF INFORMATION ABOUT CANCER CLINICAL TRIALS

What Are Clinical Trials All About?

This booklet for consumers provides information about clinical trials—what they are and how they are structured—and discusses key issues involved in participating, such as benefits and possible risks, informed consent, and things to know about before joining a trial. The booklet is available in English and Spanish from the Cancer Information Service at 1-800-4-CANCER.

The Cancer Information Service

This NCI program is a toll-free telephone service (1-800-4-CANCER) for cancer patients and their families and friends, the general public, and health care professionals. The staff can answer questions in

English and Spanish, send free NCI information booklets about cancer, and provide information about local resources and services.

FOR MORE INFORMATION

For more information about the Clinical Trials Accessibility Working Group and its activities, please contact:

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Trial News (<http://www.nabco.org>)

This section of the National Alliance of Breast Cancer Organizations (NABCO) home page provides a current list and brief summaries of breast cancer trials, including telephone numbers of investigators. For more information on a specific trial, users may click on the link in the NABCO description to be connected to NCI's new clinical trials page (http://cancertrials.nci.nih.gov/NCI_CANCER_TRIALS), where they find a glossary of technical terms. In addition, patients can print the clinical trials information for review with their physicians.

PDQ (Physician Data Query)

PDQ is a computerized database developed by NCI that provides doctors with access to current information about the latest cancer treatments, descriptions of clinical trials that are open for enrollment, and the names of organizations and doctors involved in cancer care. Patients and the general public also can gain access to PDQ by calling the Cancer Information Service and requesting a data search.

The American Cancer Society

The American Cancer Society (ACS) is a volunteer organization with local units all over the country. It supports research, conducts educational programs, provides booklets about cancer, and offers many services to patients and their families. ACS can be reached by calling 1-800-ACS-2345.